ORIGINAL CONTRIBUTION

Magnetic Anal Sphincter Augmentation in Patients With Severe Fecal Incontinence

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BACKGROUND: Fecal incontinence is a common, distressing condition with limited surgical options.

OBJECTIVE: This study examines the results of magnetic sphincter augmentation in patients with severe fecal incontinence.

DESIGN: This was a single-center, prospective, nonrandomized investigation.

SETTING: This study was conducted in a private colorectal practice.

PATIENTS: The cohort included all of the patients implanted with magnetic sphincter augmentation between January 2012 and October 2013.

INTERVENTION: Magnetic sphincter augmentation was studied.

MAIN OUTCOME MEASURES: Adverse events, symptom severity, quality of life, bowel diary, and manometry data were collected.

RESULTS: Eighteen patients (15 women), with mean age of 69 years (range, 31–91 years), were implanted with magnetic sphincter augmentation. Follow-up ranged from 353 to 738 days. Previous treatment consisted of peripheral nerve evaluation test in 10 patients (56%), 2 patients (11%) with previous permanent sacral nerve stimulation, and 1 patient (6%) with previous implantation of an artificial bowel sphincter. Implantation was successful in 17 (94%) of 18 patients. Five patients (29%) had postoperative pain, and 5 patients (29%) had temporary swelling and erythema in both gluteal regions after the implantation. No devices were explanted during the follow-up. Cleveland Clinic Incontinence Score decreased from a mean of 17.5 (range, 14.0–20.0) to 7.3 (range, 0–12.0), and Fecal Incontinence Quality of Life scores improved in all of the domains. Bowel diary results showed that 76% of the patients with implants experienced a ≥50% reduction in the number of fecal incontinence episodes per week. Manometry at 6 months after implantation showed increased mean resting and squeeze pressures.

LIMITATIONS: This study does not allow for comparison between surgical treatments and involves a limited number of patients.

CONCLUSIONS: Magnetic sphincter augmentation shows consistent results for the treatment of severe fecal incontinence in this patient group. The surgical procedure is straightforward as compared with other implantable devices. The safety profile is acceptable. Magnetic sphincter augmentation is a promising new treatment with the potential to become a first-line surgical therapy for patients with severe fecal incontinence.

KEY WORDS: Anorectal; Pelvic floor.

Because of the complex nature of maintaining fecal continence, none of the current theories on fecal incontinence (FI) can adequately explain it.[1] The prevalence of FI varies, depending on the population being examined. In the literature, a range from 1% to 20% in American women is quoted.[2–4] Affected patients experience a profound loss of quality of life, with a possible consequence of complete social isolation. The treatment options, especially surgical procedures for severe FI, are limited, and there is insufficient evidence to allow quality comparisons among the various surgical approaches.[5] The choice of operation should take into consideration multiple factors, including patient anatomy, previous operations, stool consistency, and patient compliance. Therefore, it is necessary to individualize the treatment plan for each patient.[6]

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Magnetic sphincter augmentation (MSA) is a platform therapy designed to add support through the magnetic attraction of beads placed around the circumference of a weakened sphincter. Initially used in the treatment of gastroesophageal reflux disease, the technology is now being used in the treatment of severe FI.

MSA was first described by Lehur and colleagues[7] in 2010 in a multicenter feasibility study. Since then, a few studies from the same center have demonstrated repeatable results from the implantation of the MSA device. The objective of this study was to present our single-center experience with the MSA device in patients with severe FI.

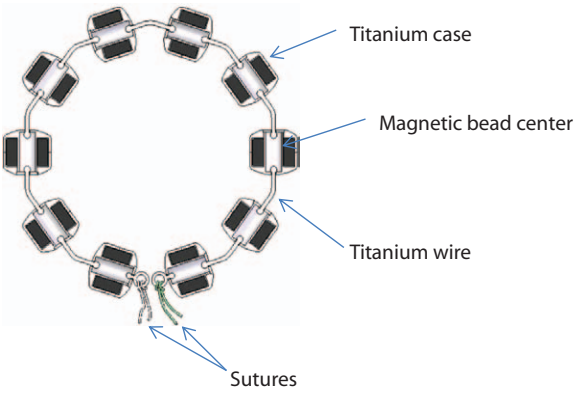

Figure 1. Cross-section of the magnetic sphincter augmentation device. Reprinted with permission from Torax Medical.

MATERIALS AND METHODS

Study Population

Each patient underwent proctologic examination consisting of detailed medical history, visible inspection, rectal examination, anoscopy, rectoscopy, and colonoscopy to exclude other colonic diseases. Endoanal ultrasound was also performed to rule out potential tumors but not to measure a sphincter defect. The validated questionnaires regarding symptom severity (Cleveland Clinic Incontinence Score [CCIS]) and quality of life (Fecal Incontinence Quality of Life [FIQoL] score) were completed by the patient and reviewed at the following office visit for accuracy and completeness.

All of the patients with severe FI treated with the MSA device from January 2012 to February 2013 were included through a prospectively maintained database. Data were collected on patient demographics, etiology of FI, number of pregnancies/births, history of abdominal and pelvic floor surgeries, and previous treatment of FI. Only patients with severe FI who had failed previous treatments were considered for MSA implantation. Patients with obstructed defecation syndrome, full rectal prolapse, IBD, previous pelvic radiation, scarred perineum, and history of anorectal fistula were excluded. All of the patients were informed of the risks and benefits of this therapy, as well as alternative treatments, before surgery.

Magnetic Sphincter Augmentation

The FENIX Continence Restoration System (Torax Medical Inc, Shoreview, MN) consists of a permanent implant that is designed to treat FI by reinforcing weakened anal sphincter muscles and increasing the pressure in the anal canal. The setup and mechanisms of the MSA device have been described in detail previously.[7,8] In summary, the device is a small, flexible band of individually linked titanium beads with magnetic cores (Fig. 1).

The device is surgically placed around the anal canal in the closed position (Fig. 2). With normal straining, the beads will separate temporarily to allow the intentional passage of stool (Fig. 3). The magnetic attraction between the beads then brings the device back to the closed position to prevent involuntary opening of the anal canal that may lead to incontinence.

Operative Procedure

Patients underwent standard preoperative cleaning of the rectum with 300 mL of phosphate enema. No prophylactic antibiotics were used. All of the patients underwent surgery under general anesthesia and in the lithotomy position. During the operation, special care was taken to prevent infection by flushing the surgical site with antiseptic povidone-iodine solution and multiple changes of gloves. After a single perineal incision, a 5-cm–deep dissection of the perineal body was performed. In women, this dissection was into the rectovaginal septum. Then, left and right fossa ischiorectalis were tunneled, aiming to the tip of the coccyx as a dorsal landmark. After completion of the tunnel, the sizing tool was introduced under digital control and used to determine the properly sized device. The sizing tool was removed and the device was intro-

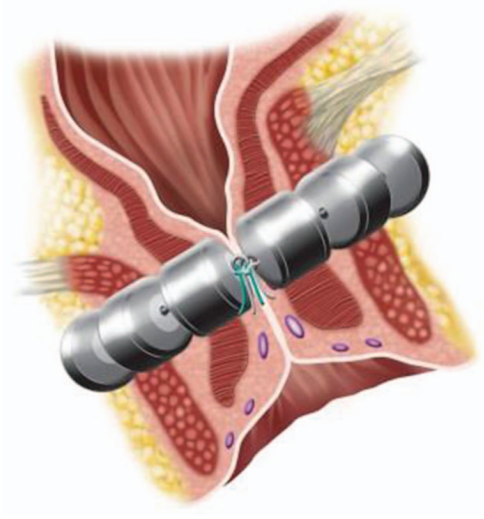

Figure 2. The magnetic sphincter augmentation device in closed position. Reprinted with permission from Torax Medical.

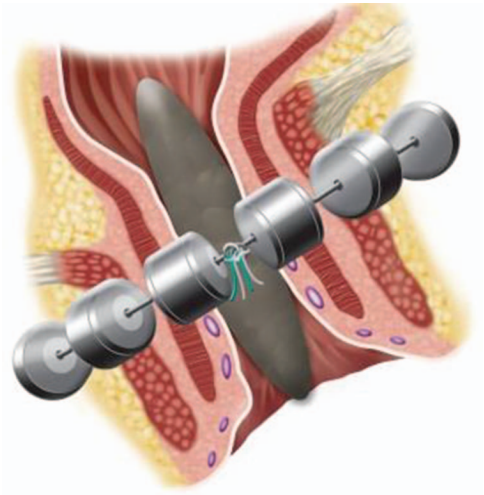

Figure 3. The magnetic sphincter augmentation device in open position, allowing stool to pass. Reprinted with permission from Torax Medical.

duced. The correct position and contact of the beads were verified using fluoroscopy. To ensure that the device was not too loose, seeing 1 to 3 beads separated on the x-ray was acceptable. The MSA device was then closed by tying the sutures at each end of the device. The perineal incision was then closed. A final fluoroscopy control was made at the end of the procedure.

Pain medication (eg, diclofenac or metamizole) was prescribed as needed. No dietary restriction was needed. The patient was observed in the hospital to make sure that the surgical wound was healing and the patient was able to pass stool.

Assessment

Evaluation of the efficacy of the MSA device was based on the CCIS (20 points)[9] and the FIQoL score using 4 components (lifestyle, coping/behavior, depression, and embarrassment).[10] Patients were assessed at baseline and at 6, 12, and 24 months after the procedure.

Prospectively collected data included procedure time; length of stay; and intraoperative, postoperative, and late complications. Statistical analysis was performed using Student *t* test and Wilcoxon test, with a p value <0.05 as significant.

RESULTS

In our institution, 18 patients, 15 women and 3 men, with severe FI were selected for an implantation of the MSA device between January 2012 and February 2013. All 18 of the patients had a history of FI of ≥2 years. The mean age of the patients was 69 years (range, 31–91 years). Fifteen patients had previous pelvic floor or proctologic surgery. The mean number of births for the 15 patients who were women was 2 (range, 0–5 births). All of the patients had passive FI.

Table 1. Summary of patient surgical history

Surgical procedure	*No. of patients*	*Percentage (N = 18)*
Hysterectomy	4	22.0
STAAR/Transtar	7	39.0
Sigmoid resection	3	17.0
Colon resection	1	5.5
Urogenital prolapse repair	2	11.0
Surgical FI treatment		
Failed SNS PNE	8	44.0
Failed SNS implant	2	11.0
Failed ABS	1	5.5

STARR = stapled transanal rectal resection; FI = fecal incontinence; SNS = sacral nerve stimulation; PNE = percutaneous nerve evaluation; ABS = artificial bowel sphincter.

Several patients (39%) had previous rectal resection for rectal prolapse and outlet constipation, primarily stapled transanal rectal resection and Transtar. No patient had undergone previous pelvic radiation, a precaution for the implantation of this device. Of note, of the 10 patients who had peripheral nerve evaluation, 2 went on to sacral nerve stimulation (SNS). One patient had an artificial bowel sphincter (ABS) implanted and removed because of erosion before the MSA implantation. Table 1 summarizes the patient surgical history relevant to FI. Table 2 summarizes the etiologies of the patients in this series.

The mean operative time was 32 minutes (range, 21–46 minutes), and the median hospital stay was 5 days (range, 3–6 days). The mean device size implanted was 18 beads (range, 17–20 beads). The mean number of bead separations or gaps during intraoperative fluoroscopy control was 2 (Fig. 4).

Mean follow-up in this cohort of patients was 607 days (range, 353–738 days), with 7 patients having completed their 2-year follow-up and all other patients with >1 year of follow-up. All of the MSA devices remain implanted.

Complications

In 1 patient, the implantation was aborted because of an intraoperative rectal perforation during preparation of the circular tunnel. The patient recovered without any long-term consequences. Four patients had superficial wound dehiscence postoperatively, which were treated conservatively with antibiotics and resolved. Five patients had perianal and gluteal swelling and erythema, which

Table 2. Summary of FI etiology

Etiology	*No. of patients*	*Percentage (N = 18)*
Obstetric injury	6	33.0
Idiopathic	4	22.0
Surgical injury	3	17.0
Obstetric/neurogenic	2	11.0
Obstetric/surgical	2	11.0
Neurogenic/surgical	1	5.5

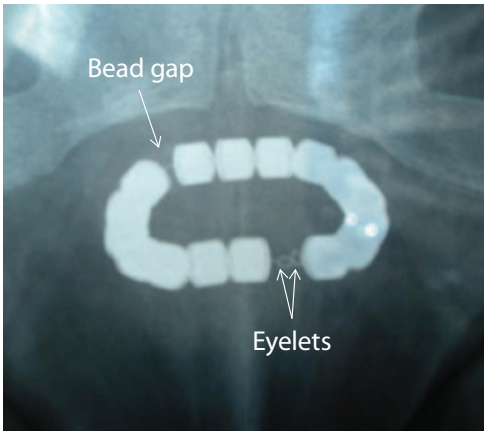

Figure 4. Intraoperative fluoroscopy showing eyelets and 1 open gap between beads.

were treated conservatively and resolved as well. One patient had vaginal bleeding, which stopped spontaneously within the first postoperative week. A later gynecologic examination confirmed a pathologic vaginal lining as the reason for bleeding. No other early or late adverse effects were observed.

The MSA device of the patient, who had the first implantation in our series, was cut accidentally by another surgeon during an abdominal rectal prolapse repair because of recurrent prolapse. This occurred 18 months after the device implantation. The device has not been explanted, and the patient has since had a colostomy for incontinence and continues to be followed (Fig. 5).

Functional and Quality-of-Life Outcomes

At baseline, the mean CCIS was 17.5 (range, 14.0–20.0). After the implantation, CCIS decreased to 7.3 (range, 0–12.0). No deterioration was seen during further follow-up (Fig. 6). Table 3 shows the breakdown of changes in the CCIS over time by individual component.

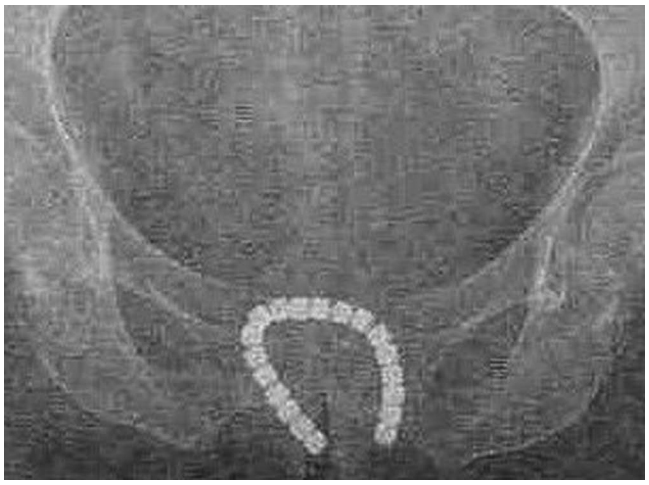

Figure 5. Image of transected magnetic sphincter augmentation device.

The postoperative FIQoL score showed a significant improvement in all 4 components when compared with preoperative values. There was no deterioration after 6, 12, and 24 months (Fig. 7).

Each patient was asked to complete a bowel diary for ≥2 weeks. At 6 months postimplantation, the number of FI episodes decreased from a mean of 8.0 episodes (±1.4 episodes) per week at baseline to a mean of 2.8 episodes (±2.2 episodes). An improvement of ≥50% in the number of FI episodes per week was reported by 76% (13/17) of the patients.

Anorectal manometry was performed on each of the patients. At baseline, the mean resting pressure was 16.0 ± 10.7 mm Hg), and the mean squeeze pressure was 34.0 ± 15.8 mm Hg. At 6 months after implantation, manometry was repeated, and the mean resting pressure increased by 50% to 24.0 ± 10.6 mm Hg) and mean squeeze pressure increased by 21% to 41.0 ± 17.4 mm Hg. Although minor incontinence was reported in 16 of 17 patients, all of the patients were satisfied with their postoperative condition. None of the patients (except the one whose device was accidentally transected) have gone on to have further procedures for FI.

DISCUSSION

The treatment of severe FI remains challenging, with limited options before resorting to a permanent colostomy. The challenge for a successful treatment of FI and an optimal outcome is to choose the most effective treatment for the individual patient.[6] In our own institution, prevalence of FI is 12%, and to date only 2% of affected patients have been treated by surgical procedures.

MSA was first developed for the treatment of gastroesophageal reflux disease.[11,12] In 2008, MSA for use in FI was introduced in a feasibility study,[7] with promising early results. These results were confirmed by Barussaud and colleagues[13] in their 2-year follow-up study.

In our institution, the MSA was implanted in 17 patients, starting with the first implantation in 2012. Although the number of patients implanted is limited, our results suggest that the implantation of the MSA device is safe and the average operation time is short. In the first 5

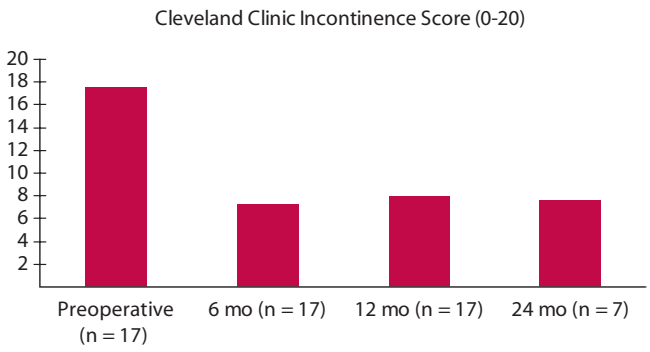

Figure 6. Cleveland Clinic Incontinence Score at baseline and during follow-up.

Table 3. Cleveland Clinic Incontinence Score by component

	Baseline (n = 17)	*6 mo (n = 17)*	*p*	*12 mo (n = 17)*	*p*	*24 mo (n = 7)*	*p*
Solid stool	2.7	0.4	<0.001	0.0	<0.001	0.3	0.04
Liquid stool	3.8	2.1	<0.001	1.9	<0.001	1.9	0.01
Gas	3.9	2.0	<0.001	2.1	<0.001	2.1	0.01
Pads	3.9	2.5	0.002	3.3	0.05	2.9	0.08
Lifestyle	3.1	0.4	<0.001	0.6	<0.001	0.7	0.30
Total	17.4	7.3	<0.001	7.8	<0.001	7.6	<0.001

cases, gluteal and perianal erythema and swelling were observed, which were treated conservatively with analgesics and cool compresses for the first week after the implantation, resulting in complete resolution. A possible reason for this finding is a chemical reaction of octenidin solution, which was used for disinfectant. After using povidone-iodine solution, no further reaction was observed. Four patients with superficial wound dehiscence were treated with antibiotics and resolved. A complication during additional follow-up was the iatrogenic transection of the MSA device by a surgeon when performing an abdominal rectopexy for recurrent rectal prolapse. This operation was performed in another hospital, and the surgeon was not familiar with the device. After the operation, the patient noticed a worsening of her continence function. X-ray control confirmed the transection of the MSA device. The patient did not want to have the device removed and continues to be followed. No case of device infection or erosion has been observed, and the MSA device remains implanted in all of the patients.

The choice of the number of beads is a very important step in the operation, and this step has been modified by using a new sizing tool. When controlling the correct size and fit of the MSA, it is recommended that 1 to 3 gaps between the beads be visible during intraoperative fluoroscopy. This is to ensure that the device is not too loose. The attractive force of the magnetic beads will eventually bring all of the beads together.

Wong and colleagues[14] compared their results of the MSA with the ABS. They concluded that both devices are effective for the management of FI with a more simple implantation of the MSA and a trend toward better continence in patients with an ABS. The ABS has historically been associated with a significant rate of infection and revision, 34% and 25%.[15] The rate of infection in this small series is much less and was responsive to antibiotics. There were no revisions or explants. The implantation of the MSA device is a much less invasive procedure than the ABS. There is only 1 dynamic component placed around the anal canal versus the ABS with 3 components. The ABS also has a silicone cuff that is placed around the anal canal through a larger tunnel. In addition, there is a reservoir that is placed through an abdominal incision and a patient-activated pump that is surgically placed in the scrotum or labia. The procedure time and exposure to potential contaminants are 2 to 3 times for ABS versus MSA. There are 2 additional skin incisions and much more hardware to implant with ABS.

In a second study, the same group[16] compared the MSA with SNS and found that both methods were equally

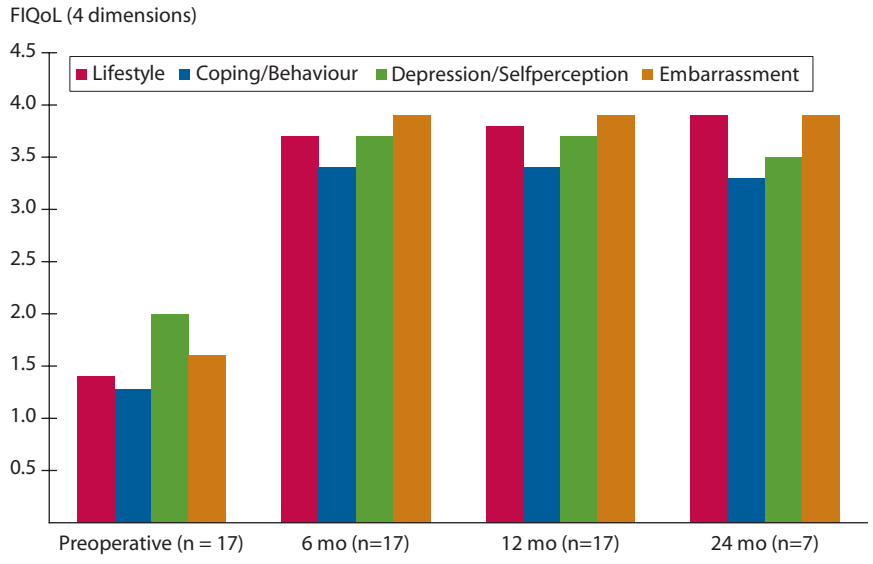

Figure 7. Fecal Incontinence Quality of Life score with 4 dimensions preoperatively and 6, 12, and 24 months after the magnetic sphincter augmentation implantation.

effective, but one advantage of the MSA over both the ABS and SNS is that it functions immediately after the operation without the need for patient or physician interaction with the device. The device is sized to the individual and should not need any adjustments. There is no activation or programming required. This is a significant advantage of MSA over both ABS and SNS.

Recently, Bridoux and colleagues[17] reported their results of 7 MSA implantations. In 5 patients, the device was removed, 3 times as a consequence of infection and in 2 cases because of perineal pain and an unsatisfactory result. CCIS only improved from 16.0±3.2 to 12.4±4.1. In their group, the median age of patients was 57 years (range, 31–65 years). In our series, patients were >12 years older and potentially less physically active. In general, the patients treated in the series by Bridoux and colleagues[17] may have been more challenging to treat with MSA. There were 2 patients who had failed ABS. For example, the majority of the patients in the article by Bridoux and colleagues[17] (4/7) had an etiology related to fistula surgery. None of the patients in our series had undergone fistula surgery. An older, more sedentary patient may do better with MSA, but more studies will need to be done to determine the best candidates for this therapy.

This was a prospective study, and all of the patients who underwent an implantation of the MSA were selected because they were thought to be good candidates. Our results should not be used to directly compare the MSA with other procedures for surgical treatment of severe FI. However, what this study highlights is that, after 2 years of follow-up, MSA provides a safe surgical alternative in the management of severe FI with satisfactory results. It indicates that the first results reported by Lehur and colleagues[7] are reproducible. To date, <200 MSAs have been implanted worldwide. The perfect indication for the MSA device has yet to be determined. In addition, its role relative to SNS needs further study, as well as its place in the complete treatment algorithm for severe FI. More studies with larger numbers of implantations and a longer follow-up are all necessary to fully understand the role of the MSA in the surgical treatment of FI.

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